REMARKS

The Office Action mailed May 12, 2009 has been received and carefully reviewed. In this Amendment & Response, claims 1 and 3-12 are amended. New claims 13 and 14 have been added. Entry of the amendment is requested. Upon entry, claims 1-14 are pending in the Application. Reconsideration is hereby requested.

Support for the Amendment:

Claims 1 and 3-12 have been amended to remove reference numerals. No new matter has been added.

Claims 1, 3, 5 and 12 have been amended to clarify antecedent basis for the claims. No new matter has been added.

Claim Rejections under 35 U.S.C. §112:

In the Office Action, claims 1-12 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to provide antecedent basis for certain terms used in the claims. Specifically, claims 1 and 3 are rejected because no antecedent basis for the term "the membrane nebulizer" exists. Additionally, claim 5 is rejected for lack of antecedent basis for the term "the framework of the operating system of the PDA." Lastly, the term "the membrane aerosol generator" of claim 12 is cited as lacking antecedent basis. Accordingly, claims 1, 3, 5 and 12 have been amended to address these issues. Withdrawal of the rejections is requested.

35 U.S.C. §103(a) rejections over Stenzler in view of Grey:

In the Office Action, claims 1-12 are rejected over U.S. Patent 6,435,175 to Stenzler in view of U.S. Patent 7,111,756 to Grey. This rejection is traversed.

Claim 1 is directed to an aerosol therapy device having a nebuliser and a PDA comprising a communication device for transferring the therapy data processed in relation to

signals to the PDA and for receiving control data from the PDA, and control means for activating said aerosol generator based on the control data received from the PDA. Claim 1 further specifies that the PDA is equipped with a communication device for receiving the therapy data transmitted by the nebuliser and for transferring control data to the nebuliser, and a device for generating control data by the therapy-related evaluation of the transmitted therapy data.

Stenzler discloses a pulmonary drug delivery device 2 comprising an electronic control unit 4 and a hand piece 50 which contains a cartridge 70 and an inhalation sensor 58. The electronic control unit 4 controls the operation of the drug delivery device 2 with information stored on an information storage element 76 located within cartridge 70. Information storage element 76 can contain the drug delivery protocol and can be tailored to a particular patient or drug. See column 4, lines 20-39 of Stenzler. Located in the electronic control unit 4 is a communications port 32 that is used to transmit data from the device 2 to an external location or device. See Stenzler at column 3, lines 40-47.

Grey discloses a hand held dispensing device for controlled or remote controlled dispensing of medicaments. The hand held dispensing device of Grey is configurable with means for communicating with a separate standard computing device, for example a personal computer, palmtop, PDA or WAP telephone, such as via an infra-red port. See Grey at column 3, lines 30-35.

Claim 1 is not obvious over Stenzler and Grey at least because neither reference, alone or in combination, teaches or suggests the claimed invention. Specifically, neither Stenzler nor Grey teach or suggest an aerosol therapy device having a nebuliser and a PDA wherein the PDA is equipped with a communication device for receiving therapy data transmitted by the nebuliser and for transferring control data to the nebuliser wherein a device within the PDA generates control data by a therapy-related evaluation of the transmitted therapy data, as recited in claim 1. As described at the first full paragraph on page 4 of the translated specification, the therapy-related evaluation of claim 1 "is to be understood as all those measures and means that are realised in the PDA to examine the data in respect of the therapy so that conclusions regarding the therapy can be made on the basis of the examination results and the therapy can thus be influenced in a controlling manner based on these results." As such, claim 1 relates to an aerosol

therapy device in which a PDA can not only receive therapy data from the nebulizer, but can also send control data back to the nebuliser during the same therapy session based upon an analysis of the input therapy data such that closed loop therapy control is possible.

In contrast to claim 1, Stenzler discloses an electronic control unit 4 that controls the operation of the drug delivery device which is fully functional only if a cartridge 70 is inserted into hand piece 50. Once the cartridge 70 is inserted into the hand piece 50, the control unit reads instructional data held on a storage element 76 provided on the cartridge and begins with the control operation via a signal from an inhalation sensor 58 included in the hand piece 50. See Stenzler at column 6, lines 13-19 and column 7, lines 4-20. The specific operation of the nebuliser in Stenzler, such as the required dosage of the drug that is to be administered, can be modified by storing drug or patient specific data on the storage element 76. See Stenzler at column 4, lines 20-39. Additionally, the operation of the nebuliser can be enabled or cancelled through the control unit 4 based upon buttons located on the control unit 4. See Stenzler at column 3, lines 29-39. Therefore, Stenzler describes an open loop control system wherein the output of the nebuliser is controlled based upon predetermined data on the storage element 76 and wherein the output of the nebuliser during the therapy session is not modified by the control unit 4. Thus, Stenzler discloses a system unable to modify a therapy session based upon data collected during the therapy session itself. As such, Stenzler fails to teach or suggest an aerosol therapy device having a PDA device configured for receiving therapy data transmitted by a nebuliser and for transferring control data to the nebuliser wherein a device within the PDA generates control data by means of a therapy-related evaluation of the transmitted therapy data, as recited in claim 1.

Moreover, as conceded in the Office Action at page 3, Stenzler does not disclose a PDA control unit of any kind. Although Stenzler does disclose a communications port 32, which is used to transmit patient compliance information to an output device 180, Stenzler does not teach or suggest that output device 180 transmit any information to the control unit 4. (see col. 7, line 49 to col. 8, line 8). As such, Stenzler fails to teach or suggest the PDA of claim 1.

With respect to Grey, there is no further disclosure that alleviates the cited shortcomings of Stenzler. Although Grey does discuss the use of a PDA device, the configuration of the

disclosed PDA is for an entirely different purpose. Specifically, Grey states that the PDA allows the patient to establish a dialogue between a host computer or a physician and makes it possible to report past use of the device while simultaneously "enabling the patient to fill in a questionnaire, or to enter into the system a query about their condition or a report of current state of health." See column 3, lines 30-46. Grey does not refer to a PDA at any other place in the specification. As such, Grey fails to teach or suggest a PDA that is equipped with a device for generating control data by a therapy-related evaluation of data transmitted to the PDA by the nebulizer, as recited in claim 1.

For at least the aforementioned reasons, claim 1 is patentable over Grey, Stenzler and a combination of Grey and Stenzler. As claims 2-12 depend from claim 1, they are likewise patentable for at least the same reasons. Withdrawal of the rejection is requested.

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers or any future reply, if appropriate. Please charge any additional fees or credit overpayment to Deposit Account No. 13-2725.

Respectfully submitted,

MERCHANT & GOULD P.C.

Dated: 9/14/09

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